

WE CLAIM:

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A biosensor device which comprises:

a strip of a substrate having at least two zones wherein a

5 (1) first of the zones contains a first capture reagent bound to or as a moiety of the substrate in a defined area and spaced apart electrodes defining sides of the defined area for providing an electrical bias to the defined area; and

10 (2) a second of the zones containing a fluid transfer medium for supplying a fluid to the first zone, wherein the second zone comprises a second defined area containing a second capture reagent bound to or as a moiety of an electrically conductive polymer, wherein
15 when a fluid sample containing an analyte is bound by the second capture reagent to form a complex, the complex migrates to the first zone in the medium and the analyte is bound by the first capture reagent thereby altering a conductivity or resistance of the defined
20 area in the first zone as measured between the electrodes to detect the analyte.

-2-

The device of Claim 1 wherein the device further comprises a third zone adjacent to the first zone into which the fluid is absorbed after passing through the first defined area of the first zone.

A method for detecting an analyte in a fluid sample which comprises:

- (a) providing a biosensor device which comprises:
a strip of a substrate having at least two zones

wherein a

(1) first of the zones contains a first capture reagent bound to or as a moiety of the substrate in a defined area and spaced apart electrodes defining sides of the defined area for providing an electrical bias to the defined area; and

(2) a second of the zones containing a fluid transfer medium for supplying a fluid to the first zone, wherein the second zone comprises a second defined area containing a second capture reagent bound to or as a moiety of an electrically conductive polymer, wherein when a fluid sample containing an analyte is bound by the second capture reagent to form a complex, the complex migrates to the first zone in the medium and the analyte is bound by the first capture reagent thereby altering a conductivity or resistance of the defined area in the first zone as measured between the electrodes;

(b) applying the sample to the second defined area of the second zone so that when the analyte binds to the first and second capture reagents in the first zone, the conductivity or resistance of the first defined area is altered due to the presence of the conductive polymer to detect the analyte.

-29-

-5-

The method of Claim 4 wherein the device further comprises a third zone adjacent to the first zone into which the fluid is absorbed after passing through the first defined area of the first zone.

-6-

The method of Claims 4 or 5 wherein the first defined area has a dimension between the electrodes of 1.0 mm or less between which the conductivity is measured.

A system for detecting an analyte in a fluid sample which comprises:

(a) a biosensor device which comprises:

a strip of a substrate having at least two zones wherein a

(1) first of the zones contains a first capture reagent bound to or as a moiety of the substrate in a defined area and spaced apart electrodes defining the sides of the defined area for providing an electrical bias to the defined area; and

(2) a second of the zones containing a fluid transfer medium for supplying a fluid to the first zone, wherein the second zone comprises a second defined area containing a second capture reagent bound to or as a moiety of an electrically conductive polymer, wherein when a fluid sample containing an analyte is bound by the second capture reagent to form a complex, the complex migrates to the first zone in the medium and the analyte is bound by the first capture reagent thereby altering a conductivity or resistance of the defined area in the first zone as measured between the electrodes;

(b) electrical means for supplying an electrical bias between the electrodes; and

(c) measuring means for determining a change in the conductivity or resistance of the first area before and after application of the sample in the second zone to detect the analyte.

A biosensor device which comprises:

a strip of a substrate having at least two zones wherein a

5 (1) first of the zones contains a first antibody bound to the substrate in a defined area and spaced apart electrodes defining sides of the defined area for providing an electrical bias to the defined area; and

10 (2) a second of the zones containing a fluid transfer medium for supplying a fluid to the first zone, wherein the second zone comprises a second defined area containing a second antibody bound to an electrically conductive polymer, wherein when a fluid sample containing an antigen which is bound by the second antibody bound to the conductive polymer to form a complex, the complex migrates to the first zone in the medium and the antigen is bound by the first antibody thereby altering a conductivity or resistance of the defined area in the first zone as measured between the electrodes to detect the antigen.

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The device of Claim 8 wherein the device further comprises a third zone adjacent to the first zone into which the fluid is absorbed after passing through the first defined area of the first zone.

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The device of any one of Claims 8 or 9 wherein the first defined area has a dimension between the electrodes of 1.0 mm or less.

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A method for detecting an antigen in a fluid sample which comprises:

(a) providing a biosensor device which comprises:

5 a strip of a substrate having at least two zones wherein a

(1) first of the zones contains a first antibody bound to the substrate in a defined area and spaced apart electrodes defining sides of the defined area for providing an electrical bias to the defined area; and

10 (2) a second of the zones containing a fluid transfer medium for supplying a fluid to the first zone, wherein the second zone comprises a second defined area containing a second antibody bound to an electrically conductive polymer, wherein when a fluid sample containing an antigen which is bound by the second antibody bound to the conductive polymer to form a complex, the complex migrates to the first zone in the medium and the antigen is bound by the first antibody thereby altering a conductivity or resistance of the defined area in the first zone as measured between the electrodes;

15 20 25 (b) applying the sample to the second defined area of the second zone so that when the antigen binds to the first and second antibodies and the conductivity or resistance of the first defined area is altered due to the presence of the conductive polymer to detect the antigen.

-34-

-12-

The method of Claim 11 wherein the device further comprises a third zone adjacent to the first zone into which the fluid is absorbed after passing through the first defined area of the first zone.

-13-

The method of Claims 11 or 12 wherein the first defined area has a dimension between the electrodes of 1.0 mm or less between which the conductivity is measured.

A system for detecting an antigen in a fluid sample which comprises:

(a) a biosensor device which comprises:

a strip of a substrate having at least two zones wherein a

(1) first of the zones contains a first antibody bound to the substrate in a defined area and spaced apart electrodes on either of the sides of the defined area for providing an electrical bias to the defined area; and

(2) a second of the zones containing a fluid transfer medium for supplying a fluid to the first zone, wherein the second zone comprises a second defined area containing a second antibody bound to an electrically conductive polymer, wherein when a fluid sample containing an antigen which is bound by the second antibody bound to the conductive polymer to form a complex, the complex migrates to the first zone in the medium and the antigen is bound by the first antibody thereby altering a conductivity or resistance of the defined area in the first zone as measured between the electrodes;

(b) electrical means for supplying an electrical bias between the electrodes; and

(c) measuring means for determining a change in the conductivity or resistance of the first area before and after application of the sample in the second zone to detect the antigen.

-36-

-15-

The system of Claim 13 wherein the device further comprises a third zone adjacent to the first zone into which the fluid is absorbed after passing through the first defined area of the first zone.

-16-

The device of Claim 1 or 2 wherein a third substrate for applying the fluid containing the analyte which is applied prior to being introduced into the second zone.

-17-

The method of Claims 4 or 5 wherein a pad for applying the fluid containing the analyte which is applied prior to being introduced into the second zone.

-18-

The system of Claim 7 or 8 wherein a pad for applying the fluid containing the analyte is applied prior to being introduced into the second zone.

-19-

The device of Claim 8 or 9 wherein a pad for applying the fluid containing the analyte is applied prior to being introduced into the second zone.

-20-

The method of Claim 11 or 12 wherein a pad for applying the fluid containing the analyte is applied prior to being introduced into the second zone.

-37-

-21-

The system of Claim 14 or 15 wherein a pad for applying the fluid containing the analyte is applied prior to being introduced into the second zone.

-22-

The device of Claim 1, or 2 wherein there is a multiple array so that multiple analytes can be detected simultaneously from the same sample.

-23-

The method of Claim 4 or 5 wherein there is a multiple array so that multiple analytes are detected simultaneously from the same sample.

-24-

The device of Claim 8 or 9 wherein there is a multiple array so that multiple analytes are detected simultaneously from the same sample.

-25-

The method of Claim 11 or 12 wherein there is a multiple array so that multiple analytes are detected simultaneously from the same sample.

-26-

The system of Claim 14 or 15 wherein there is a multiple array so that multiple analytes can be detected simultaneously from the sample.